

4,865,591

5

Torrington type mechanism is used. However, it is preferred that the plunger carry an axial series of transverse ribs, grooves or teeth which engage with corresponding teeth carried by the drive mechanism. The teeth can extend for substantially the full length of the plunger, but this need not be the case and the terminal portions of the plunger can have a plain surface. Preferably, the teeth are of a saw tooth form with the scarp or undercut face of the tooth facing rearwardly. It is preferred that the axial distance between adjacent teeth corresponds to the distance the piston is to move in the cartridge to dispense a unit dose, for example 1 or 2 IUs, of insulin.

The drive mechanism for present use is one which can be completely disengaged from the plunger to permit relative axial movement between them and so that there can be no drive between the drive mechanism and the plunger until the drive is positively re-engaged. However, when the drive mechanism is engaged, it locks onto the plunger so that there is substantially no relative movement between them. A suitable drive mechanism may thus incorporate a mechanism which engages and disengages by radial movement, for example a Torrington type drive in which a series of ball or roller bearings are carried in a tapered cup around the plunger. A plug member can be moved axially into the taper to drive the balls further into the taper and thus radially inwardly to clamp onto the plunger.

However, a particularly preferred drive mechanism comprises two or more jaws arranged substantially symmetrically around the plunger and which can be moved radially inwardly to clamp onto the plunger. The radially inward faces of the jaws preferably carry teeth which co-operate with those carried by the plunger to provide a positive locked drive between the drive mechanism and the plunger when the drive is engaged. The teeth on the jaws preferably have a similar shape to those on the plunger so that there is a positive fit between them.

The jaws or other mechanism for making the positive drive connection between the drive mechanism and the plunger are preferably carried on a split collet type of structure so that they are journaled upon the plunger and can move axially thereon when disengaged. The jaws are normally urged apart by a compression spring or other bias means acting radially outwardly so that they adopt the disengaged position. In a preferred construction, the jaws extend transversely to either side of the plunger and a transverse coil compression spring is held between the jaw extensions at each side of the plunger. The springs can be held within a retaining extensible saddle piece formed integrally with each jaw extension for ease of assembly of the jaw mechanism. Alternatively, the jaws can be carried via leaf spring mountings from the collet or from another part of the drive mechanism.

Means are provided whereby a user can move the drive mechanism axially to set the dose required and to drive the plunger forward. Preferably, the forward drive is by means of a button or the like operatively associated with the plunger and extending axially from the rear end of the device, but others forms of forward drive means can be used. For example, the drive mechanism or a part operatively associated therewith can carry a radial arm which extends through an axial slot in the housing of the device, or a screw type mechanism can be used.

6

However, a particularly preferred form of drive mechanism comprises the radially moveable jaws described above carried by a split collet assembly journaled on the plunger and having springs or other bias means for urging the jaws radially outwards. The collet or the rear faces of the jaws themselves are acted on by an axially reciprocable push sleeve journaled upon the plunger. The push sleeve extends rearwardly to provide a push button mounting projecting from the rear of the device so that depression of the button causes the push sleeve and hence the jaws to move axially to drive the plunger forward. If desired, the push button or push sleeve can be recessed within the terminal portion of the housing so that a user must insert some implement, for example a removable nose cap protecting the needle of the cartridge, to be able to operate the forward drive.

The drive mechanism is engaged or disengaged by some means which requires a positive operation by the user of the device so that the drive cannot be accidentally actuated or over-ridden. Thus, where the plunger has two or more flatted surfaces, these can be inset radially from the non-flatted surfaces so that the teeth on the jaws, or the balls in a Torrington type drive coupling as described above, would not engage the flatted surfaces. The drive can therefore be disengaged by rotating the jaws or a part operatively associated therewith, for example the push sleeve described above, to align the jaws with the flatted faces, or vice versa, by a tangential movement. In this position the drive mechanism is disengaged and can move relative to the plunger, for example when it is desired to set the dosage to be dispensed. The positive operation required by the user is to rotate the push sleeve or the protruding push button connected thereto with respect to the drive mechanism and this action has to be reversed before the drive can be re-engaged.

However, a preferred form of disengagement mechanism is a cam or other radially acting mechanism which moves the drive mechanism radially in and out of engagement with the plunger. Thus, the opposed jaws described above can be moved in and out by a cam carried internally on a rotating sleeve portion of the housing within which the operating mechanism of the device is housed. In this case, the rotatable sleeve section provides both the disengagement means (the internal cams) and the actuation means (the section of the housing itself carrying the cams) in a single member.

The cams acts against the spring or other bias holding the jaws clear of the plunger and brings the jaws into engagement with the plunger. The cams also retain the jaws in the engaged position, thus locking the drive connection between the drive mechanism and the plunger, until the cams are released by rotating the sleeve section carrying them. Alternatively, the jaws can be tied to the cams so that they are moved radially in both directions by the cams without the need for a spring bias. A further form of drive disengagement and actuation mechanism is an axial or tangentially mounted lever which is mounted by means of a pivot within the wall of the housing. Raising one end of the lever causes the other end to bear radially against the jaws or other radially moveable component of the drive mechanism either directly or via an intermediate component so as to urge them radially inward and into engagement with the plunger.

Where a rotatable cammed housing section is used, it is preferred that the exterior of this section carry mark-

SAN00761629

4,865,591

7

ings or have an oval cross-section so that a user can tell the orientation of the section simply by touch.

The device incorporates a dosage selection mechanism for selecting the extent of axial travel of the disengaged drive mechanism so as to control the movement of the plunger and hence the volume of fluid discharged from the cartridge. The drive is then re-engaged and the drive mechanism returned to the datum point carrying the plunger with it. In this way the plunger moves an amount which is set by the extent to which the drive mechanism is retracted from a datum point. Since the drive is disengaged during the retraction of the drive mechanism, it is possible to correct any over- or under-shoot in the movement of the drive mechanism before the drive is re-engaged. Also, once the drive has been re-engaged, due to the fact that the plunger does not readily move rearwardly, as described below, the user cannot retract the drive mechanism or the plunger without positively disengaging the drive again. Hence tremulous or jerky operation of the device will not affect the dose to be dispensed.

The datum point for the dosage setting mechanism is preferably a stop determining the extent of forward travel of the drive mechanism or a part operationally associated therewith. Thus, the abutment of the push button driving the push sleeve against the end of the housing can provide that datum point. However, it is preferred that the datum point be provided by a stop located within the device against which the front face of the drive mechanism butts at the forward extreme of its travel. Conveniently, this stop is also the stop against which the rim of the cartridge seats when it is fitted to the device, so that the stop serves as the datum point both for positioning the cartridge to one side and for the dosage selection mechanism on the other.

The dosage selection means can operate axially, as when the push sleeve engaging the jaws described carries one or more external radial projections which but against co-operating projections carried by the housing within which the sleeve reciprocates. Rotation of the housing selects which stops will engage and hence the length of travel of the drive mechanism. Alternatively, the dosage selection mechanism can take the form of a side arm carried by the push sleeve and protruding through a stepped track or aperture in the wall of the housing which allows the sleeve to be retracted for the full length of one axial section of the track. The sleeve or a part operatively associated therewith then has to be rotated to allow the arm to move transversely into the next section where a larger dose is required.

However, we have found that a screw mechanism provides a particularly effective and accurate means for retracting the drive mechanism. Thus, for example, the dosage selection means utilises a screw sleeve journaled upon the push sleeve. The screw sleeve carries an external projection or screw thread which co-operates with an internal screw thread on the housing wall. Alternatively, the screw sleeve can have a radial projection which is journaled in a helical track or aperture in the wall of the housing of the device, or vice versa.

The screw thread can have any suitable pitch having regard to the axial movement required to achieve the minimum dose to be administered. The optimum pitch can readily be determined by simple trial and error having regard to the geometry of the device, for example so that $\frac{1}{n}$ th of a turn of the screw sleeve achieves an

8

axial travel corresponding to the axial distance between adjacent teeth on the plunger.

The screw sleeve has means by which it can be rotated by the user, for example by means of a pin or arm projecting through the wall of the device, or preferably by a collar located adjacent the end of the housing. This is connected to the sleeve through a spline coupling or the like to allow relative axial movement between the collar and the sleeve.

The forward movement of the plunger may be achieved by returning the dosage selection mechanism, for example the screw sleeve, to the datum point when the drive is re-engaged. However, this may not be easy or convenient, notably where this requires the user to rotate part of the device to achieve this, and it is preferred to employ an axial push action, e.g. by means of the push sleeve as described above. We therefore prefer that the dosage selection mechanism be demountably connected to the drive mechanism so that, when the drive is re-engaged, the connection between the dosage selection and the drive mechanisms is released. This can be conveniently achieved by providing a latch mechanism at or adjacent the forward end of the dosage selection mechanism, e.g. the screw sleeve, which latch mechanism engages the drive mechanism when the latter is in the disengaged position but which releases the drive mechanism when the latter is in the engaged position. The drive mechanism can then be driven forward independently of the dosage selection mechanism. Suitable latch mechanisms can readily be devised having regard to the specific design of the device they are to fit.

The device also comprises means whereby the dosage corresponding to a selected extent of retraction of the drive mechanism can be observed aurally or visually by a user, for example by means of a clicker mechanism. Preferably, the push sleeve or the screw sleeve carries markings correlating the dosage with the extent of axial movement. Where a screw sleeve is used, the markings are carried along a spiral path and are progressively brought into register with a window or port in the wall of the housing so that the user can see what dose is to be dispensed.

In order that a user can determine whether or not sufficient fluid remains within the container to achieve a stated amount to be dispensed, it is preferred to provide a second stop means carried by the plunger, for example at the rearward end thereof, which is engaged by the drive mechanism or push member as it is retracted. The second stop will prevent the drive mechanism or push member from being withdrawn to its full extent if the residual potential travel of the plunger is less than the desired dose. A user will detect resistance to operation of the dosage selection mechanism or will notice when the spline drive between collar 18 and the screw sleeve is over-ridden when this occurs. The user can then tell from the dose indicated as described above whether there is sufficient medicament in the cartridge to complete the required dose.

As indicated above, the plunger should not be free to move rearwardly during normal use of the device. This can be achieved by ensuring that the plunger is a frictional fit within the device. However, this may require excessive force to operate the device if the frictional forces are to overcome attempts to retract the plunger when the drive mechanism is engaged. We therefore prefer to provide some form of one way device to provide positive means for preventing the plunger from

SAN00761630

4,865,591

9

moving rearwardly when a cartridge is mounted on the device. Conveniently, this means takes the form of a second pawl arrangement which engages with the teeth on the plunger shank at the forward end of the device. Whilst this pawl can be permanently engaged, it is preferred that it be biased so as to be disengaged from the plunger when no cartridge is in position. This enables the plunger to be retracted when a cartridge has been removed from the device so that a new one can be fitted. When the cartridge is mounted on the device, it or its housing causes the second pawl to re-engage with the teeth on the plunger.

The device of the invention can be provided with other features to enhance its use. For example, the device can be put up in the form of a pen type object with a cap over the needle end of the device and a clip for mounting it in the pocket of the user.

From the above, it will be seen that from one aspect, the present invention provides a device for dispensing a controlled amount of fluid from a container, which device comprises an assembly adapted to be mounted upon a container in which a plunger is adapted to be moved axially along the container in increments so as to drive a piston within the container and thus to dispense fluid from the container, characterised in that the assembly comprises a drive mechanism adapted to be reciprocated axially of the device and to be positively engaged with the plunger for the forward stroke of the drive mechanism so as to prevent relative movement between the plunger and the drive mechanism and to move the plunger forward in the container, which drive mechanism requires a positive action to disengage it from the plunger so as to permit relative movement of the plunger and drive mechanism for at least rearward movement of the drive mechanism; in that the forward travel of the drive mechanism is limited by a fixed stop mechanism; and in that the extent of the forward stroke of the drive mechanism is selected by withdrawing the drive mechanism a selected distance from the said fixed stop.

From a preferred aspect, the invention provides a device for dispensing a controlled amount of fluid from a container by means of a piston journaled in said container, which device is characterised in that it comprises:

- a. an elongated generally cylindrical hollow body member having its forward end adapted to receive and retain the fluid container;
- b. a plunger extending axially within said body member and adapted to be moved axially in a series of individually selected increments and to bear against the piston within the container when mounted on the said body member so as to move the said piston to dispense doses of fluid from the container at each incremental movement of the plunger;
- c. a radially acting jaw member adapted to be moved into engagement with the said plunger to provide a positive drive connection between said jaw and said plunger, and to be disengaged from said plunger so as to permit relative axial movement between said plunger and said jaw;
- d. means requiring positive operation by a user of the device for engaging or disengaging said jaw from said plunger;
- e. an axially acting push sleeve journaled upon said plunger for moving said jaw forward when engaged to said plunger;
- f. axially acting dosage selection means comprising a screw thread moved sleeve journaled for axial move-

10

ment upon said push sleeve and carrying demountable means for engaging said jaw when said latter is disengaged from said plunger and for moving it rearwardly from a datum point so as to select the possible extent of forward travel of said plunger and to release said jaw when said jaw is re-engaged with said plunger for axial movement by said push sleeve; and

g. means for rotating said screw sleeve so as to select the extent of rearward movement of said screw sleeve from said datum point.

The invention also provides a device of the invention having mounted thereon a container, notably a cartridge, containing a medicament; and a medicament cartridge for use with the device, notably one housed within a housing adapted to be secured to the front end of the device of the invention.

The invention yet further provides a method for administering a fluid medicament to a patient using a device of the invention.

DESCRIPTION OF THE DRAWINGS

The device of the invention will now be described by way of illustration with respect to a preferred form thereof as shown in the accompanying drawings in which

FIG. 1 is an overall external diagrammatic view of the device;

FIG. 2 is a cross-sectional diagrammatic view through the device of FIG. 1;

FIG. 3 is a cross-sectional diagrammatic view through an alternative form of the device showing some of the components in greater detail; and

FIG. 4 is a part cut away/part perspective view of the device.

DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

The device comprises an elongated generally cylindrical housing 1 having an axial socket at one end into which a generally cylindrical cartridge 2 can be screw or push fitted. The cartridge typically has a cylindrical clear plastics or glass barrel with a hypodermic needle 3 protruding substantially co-axially from the free end thereof. A piston 4 journaled within the cartridge 2 is incrementally moved by a plunger 5 extending substantially co-axially rearwardly into the housing 1 of the device. The plunger 5 is separate from the piston and forms part of the device of the invention.

As shown in FIG. 3, the cartridge 2 can be housed in a housing 2a which is a screw fit into a collar 2b extending axially from the front end of the housing 1.

The rim of the cartridge seats against a circumferential radial shoulder or series of radial projections 2c carried internally by the housing 1 so as to locate the cartridge at a consistently fixed position with respect to the dosage selection mechanism as described below.

The device is provided with a pawl type one way mechanism which engages teeth on the plunger so as to prevent rearward movement of the plunger 5 once the cartridge is in place. This one way mechanism is shown diagrammatically as 21 in FIG. 2 and is biased to retract radially when the cartridge is removed. For example, the housing can incorporate a twist mechanism which both locks the cartridge in position and actuates the one way mechanism; or the rim of the end of the cartridge or its housing can bear against part of the one way mechanism as it seats home to actuate the one way mechanism. The one way mechanism disengages when

4,865,591

11

the cartridge is removed to allow the plunger 5 to be retracted into the device to permit a new cartridge to be mounted on the device.

A preferred form of the one way mechanism 21 is shown in FIG. 3 and comprises a pair of diametrically opposed pawls 60 carried on spring arms 61 snap fitted onto the annular shoulder 20 to extend forward of the shoulder into the axial socket in which the cartridge is mounted. The pawls 60 have an inclined rearward face 62 which bears against a correspondingly angled face 63 carried by a split collet 63 mounted around the plunger, shank and radially inward of arm 61. The collet is attached to a spring loaded sleeve 64 which is a slideable fit within the socket and is spring biased into its forward position. The front end of the sleeve 64 provides a stop 65 against which the rim 66 of the housing 2a bears as it is mounted in the device. This causes the sleeve 64 to be moved axially rearwardly to carry the inclined face of collet 63 clear of the inclined face 62 of the pawl and to bring the rear edge of collet 63 into contact with a stop 67 carried on the radially inward face of arm 61. This causes the arm 61 to flex radially inward and urge pawl 60 into engagement with the teeth on the plunger. When the housing 2a is removed to fit a new cartridge 2, this allows the sleeve 64 to move forward under the thrust of the spring so that collet 63 moves forward to release stop 67 and bears against the inclined face 62 to lift the pawl 60 clear of the teeth on the plunger. The plunger can now be retracted into the device to enable another cartridge to be fitted. By using the rear of the accurately moulded housing 2a to actuate the pawl mechanism 60-67, rather than the rim of the cartridge 2, variations in the size of the cartridge can be accommodated.

Rearwardly of shoulder 20, the body of the device houses the plunger drive mechanism, the means for engaging and disengaging the drive mechanism from the plunger and the dosage selection means. In the form of the device shown, these take the form of a series of members concentrically journaled around the plunger 5.

As shown, the housing comprises a rotatable section 6 which houses the drive engagement mechanism; a fixed section 7 containing the dosage selection mechanism and having a port 8 through which a scale 9 indicating the dose selected can be seen by the user; a further rotatable collar or sleeve 10 for operating the dosage selection mechanism; and a terminal axially operating push button 11 for driving the plunger forward to dispense the selected dose. The various sections of the housing can have any desired external shape, but it is preferred that the housing 1, sleeve 6 and section 7 have an oval external cross-section so that the relative rotational position of one with respect to the other can readily be detected by a user, notably by a blind person.

The plunger 5 preferably has a substantially circular cross-section, but can have a squared, triangular or other cross-section shape if desired. For example, as shown in FIG. 4, it may have two opposed flats along its length to guide the drive means.

The plunger 5 carries a series of circumferential ribs or teeth 22 which form an axial ratchet into which the one way mechanism 21 and the radially clampable drive mechanism described below engage. The teeth 22 are of a saw tooth form with the scarp face of the teeth directed rearwardly. Preferably, the teeth extend axially for the full length of the plunger 5. As indicated above, it is preferred that the axial distance from one tooth to

12

the next corresponds to a dosage unit for the material being dispensed.

Located to the rear of shoulder 20 is the drive mechanism and the mechanism for engaging and disengaging this from the plunger. The drive mechanism is a pawl type mechanism which is radially engageable and disengageable with the teeth on the plunger and comprises two jaws 23 and 24 diametrically opposed to one another and carrying on their radially inward faces teeth which correspond to and engage with the teeth 22 on the plunger.

The jaws are normally urged radially outwardly, as shown for jaw 24 in FIGS. 2 and 3, by transverse coil springs acting between the jaws 23 and 24 or by other bias means (not shown) so that their teeth do not engage those of the plunger, which is then free to move axially with respect to the jaws when they are in their outward position, but is locked to the jaws when they are in their radially inward position, as shown for jaw 23 in FIGS. 2 and 3.

The jaws are moved radially inward against the thrust of the coil springs by a pair of cams 6a carried on the internal face of the rotatable section 6 of the housing or formed by the narrower diameter sections of the oval cross-section of the rotatable section 6. The user has to twist section 6 to engage or disengage the jaws from plunger 5 and thus engage or disengage the drive to the plunger. If desired, section 6 can be spring biased towards the drive disengaging position so that the user always has to twist section 6 before the device can be used.

The shoulder 20, as shown in FIGS. 2 and 3, defines the forward limit of the travel of the drive mechanism and provides the datum point from which the dosage is determined. In the device shown in FIGS. 2, 3 and 4, the forward faces of jaws 23 and 24 but against the rear face of shoulder 20 to set the zero or datum point for the dosage selection mechanism.

A push sleeve 25, journaled on plunger 5 and within the dosage selection mechanism described below, acts axially on the rear faces of the jaws 23 and 24 when in their drive engaged position to drive the jaws and hence the plunger 5 forward. When the jaws are in the drive disengaged position, they still bear against the push sleeve so that they carry it axially rearwards with them during the dosage selection. The push sleeve 25 provides the mechanical link between the terminal push button 11 which a user presses and the jaws 23 and 24.

The jaws 23 and 24 are moved axially by means of a split jaw drive sleeve 26 which has forward hooks 27 which engage similar recesses 28 at the rear of the jaws and rearward hooks 29 or other flexible linkages which connect the sleeve 26 axially to the forward end of the screw sleeve 30 of the dosage selection mechanism. When the jaws are in the drive disengaged position as shown for jaw 24 in FIGS. 2 and 3, the hooks 27 and recesses 28 are engaged and the jaws can be moved axially with the screw sleeve 30. When the jaws are in the drive engaged position, as shown for jaw 23 in FIGS. 2 and 3, the hooks 27 are released from recesses 28 to permit the jaws to move axially with sleeve 25 and free from the screw sleeve 30 (as shown in FIG. 3).

The dosage selection mechanism is housed within section 7 of the housing and comprises a screw sleeve 30 journaled for rotation and axial movement upon push sleeve 25. Sleeve 30 carries an external screw thread 31 which engages a similar thread 32 carried internally by section 7 of the body of the device. Sleeve 30 is rotated

SAN00761632

4,865,591

13

and thus caused to move axially by means of collar 10 driving the sleeve through a splined drive 33 shown in FIGS. 2 and 3. Collar 10 or the window insert in port 8 preferably has a ratchet or clicker mechanism 34 to give an audible indication as the dose is selected.

Retraction of sleeve 30 carries the jaw drive sleeve 26 and the jaws 23 and 24 with it when they are in the disengaged position and the dose selected can be seen through port 8. Re-engagement of jaws 23 and 24 with the plunger, breaks the latch 27/28 and allows the push sleeve 25 and the jaws 23 and 24 to move independently of the screw sleeve 30 and the jaw drive sleeve 26.

To indicate when there is insufficient fluid left in the cartridge to achieve the next dose, a radial shoulder or stop 50 is located at or adjacent the rearward end of plunger 5. This co-operates with a corresponding stop or shoulder 51 at the forward end of the push sleeve 25. The stops engage when the push sleeve is retracted to the maximum extent possible as the plunger 5 approaches the extreme of its forward travel. The user can then see from the dose displayed at the port 8 whether the cartridge contains the requisite amount of fluid. Since the plunger drive is not engaged at this time, the user can then set the dosage mechanism to the required dose if this is less than the amount indicated as remaining in the cartridge without having to discharge fluid as with a conventional device.

Push sleeve 25 is provided with a push button end cap 11 protruding axially from the body of the device which the user depresses to drive the sleeve 25 forward within the housing until the front faces of jaws 23 and 24 but against the rear of shoulder 28. The jaws 23 and 24 can only be moved rearwardly when they have been disengaged from the teeth 22 on the plunger 5, since the one way mechanism 21 will prevent rearward movement of the plunger 5. If a user attempts to set the dosage mechanism whilst the drive is engaged, he will detect resistance to rotation of sleeve 10. If he ignores this, the spline drive 33 between collar 10 and the screw sleeve 30 will be over-ridden to release the screw sleeve to prevent damage to the mechanism. However, unless the drive is engaged, depression of button 11 will not achieve any forward movement of the jaws or discharge of fluid from the cartridge 2.

The above device can be manufactured in many suitable materials and readily lends itself to manufacture by injection moulding of suitable plastics materials with the various components being snap fits upon one another.

In operation, a user rotates the sleeve 6 to disengage the drive mechanism. Jaws 23 and 24 should be seated against the rear face of shoulder 28, the zero setting, from the previous use of the device, but the screw sleeve 30 will be at the dosage position previously selected. The user can thus see what dose was last administered where a sequence of different doses has to be administered. Sleeve 10 is rotated, say clockwise, to bring sleeve 30 to its forward position at which the latching mechanism 27/28 engages the jaws 23 and 24 and seats them firmly against the rear face of stop 20. The engagement of the latches can be used to provide an audible signal when this occurs, or the resistance to further forward movement will provide the signal to the user that the zero setting has been reached. The dosage displayed through port 8 will now read zero.

Sleeve 10 is then rotated anti-clockwise the desired number of turns, as evidenced by the number of clicks heard or by the dose displayed at the port 8, to retract

14

screw sleeve 30, the jaw drive sleeve 26 and the jaws 23 and 24 and the push sleeve 25 the desired distance with respect to plunger 5. This will also cause the push button 11 to be extended from the rear end of the device.

Sleeve 6 is then rotated to re-engage the positive drive between the push sleeve 25, the jaws 23 and 24 and the plunger 5. This action will also disengage the latch 27/28 between jaws 23 and 24 and the jaw drive sleeve 26. At this point the device is cocked and ready to dispense the desired dose from the cartridge. However, the device has required a series of positive actions to achieve this state and would not normally be retained by a user in the cocked state, but would be stored with the drive disengaged so that accidental actuation of the device can not occur.

The user then inserts the point of needle 3 into his arm, buttock or other suitable point in his body and depresses button 11 to administer the dose of insulin. The dose is administered by depressing the button fully. If the button is not depressed fully, the user can detect this and can complete the dose administration. If desired, a coloured band can be mounted around button 11 which will remain partially exposed until the button is fully depressed. Release of pressure on button 11 does not allow the plunger 5 to retract as with previous designs, so that jerky or interrupted depression of button 11 does not allow the user to pump the device to administer an excessive dose.

When the full dose has been administered, the jaws 23 and 24 will but against the rear of shoulder 28. Due to the action of the one way mechanism 21, 66-67, the blocks 23 and 24 can not be retracted and administration of a further dose of insulin is not possible until the whole process of dose selection and re-cocking of the device is carried out. The device will therefore resist accidental overdosing due to repeated pressing of button 11.

As stated above, the device of the invention finds use wherever it is desired to provide a measured dose syringe, for example in the administration of other medicaments or in dispensing accurately known amounts of a fluid, for example in blood tests or analytical work. It will also be appreciated that the device may be altered in ways which do not affect the fundamental operating concept of the device, for example by using a short plunger within the device to drive an intermediate plunger linked to a plunger carried by the piston of the cartridge; or to incorporate a flexible drive between the plunger 5 and the piston 4 so that the device of the invention is mounted at an angle to the axis of the cartridge.

What I claim is:

1. A device for dispensing a controlled amount of fluid from a container, which device comprises an assembly adapted to be mounted upon a container in which a plunger is adapted to be moved axially along the container in increments so as to drive a piston within the container and thus to dispense fluid from the container characterised in that the assembly comprises a drive mechanism adapted to be reciprocated axially of the device and to be positively engaged with the plunger for the forward stroke of the drive mechanism so as to prevent relative movement between the plunger and the drive mechanism and to move the plunger forward in the container, which drive mechanism requires a positive action to disengage it from the plunger so as to permit relative movement of the plunger and drive mechanism for at least rearward movement of the drive mechanism; in that the forward travel of the drive

SAN00761633

4,865,591

15

mechanism is limited by a fixed stop mechanism; and in that the extent of the forward stroke of the drive mechanism is selected by withdrawing the drive mechanism a selected distance from the said fixed stop.

2. A device as claimed in claim 1 which comprises:

- a. a hollow body member having one end adapted to receive and retain the fluid container
- b. a plunger, carried by said body member and adapted to be moved axially in a series of increments and to bear against the piston within the container so as to move the said piston to dispense doses of fluid from the container at each incremental movement of the plunger
- c. a push member carried by said body member for axial movement with respect to said body member and having means for achieving positive engagement with the said plunger in the forward direction of travel of the push member
- d. means requiring positive operation for releasing said positive engagement and thus permitting relative axial movement between the push member and the plunger in at least the rearward direction of travel of the said push member
- e. a stop means against which the push member or a part associated therewith butts at the extreme of the plunger's forward travel on each of its incremental movements
- f. means for withdrawing the push member or its said associated part axially from the stop means to a selected distance whereby the extent of each incremental forward movement of the plunger can be selected
- g. means for inhibiting rearward movement of the plunger whilst the container is located upon the body member

3. A device as claimed in claim 2 wherein there is provided a second stop means carried by said plunger which is engaged by the drive mechanism as it is retracted whereby the second stop member prevents the drive mechanism from being withdrawn to its full extent if the residual potential travel of the plunger is less than the desired dose.

4. A device as claimed in claim 1 wherein means are provided whereby the inhibition of the rearward movement of the plunger is removed or released when the container is removed from the body member.

5. A device as claimed in claim 4 wherein rearward movement of the plunger is prevented by a ratchet mechanism which is engaged by rotating part of the body member which also locks the container in position.

6. A device as claimed in claim 1 wherein the positive drive between the plunger and the drive mechanism is achieved by means of a radially acting mechanism which engages the shank of the axially reciprocable plunger member.

7. A device as claimed in claim 6 wherein the plunger has a series of ratchet teeth along its outer surface which are engaged directly or indirectly by a radially expandable toothed clamp member carried terminally by a sleeve push member journaled for axial movement within the device.

8. A device as claimed in claim 7 wherein the sleeve member is moveable axially by rotation thereof using a screw thread mechanism.

9. A device as claimed in claim 6 wherein the radially acting mechanism is actuated by rotation of a cam or similar mechanism to drive the radially acting mechanism

16

radially inwardly into engagement with the plunger.

10. A device for administering insulin from a cylindrical cartridge having a piston journaled therein for axial movement along the cartridge to dispense the insulin contents of the cartridge through a needle outlet into the body of a user, which device comprises:

- a. a cylindrical hollow body member having one end adapted to receive and retain the cartridge
- b. a plunger journaled within the said body member and adapted to be moved axially in a series of increments and to bear against the piston within the container so as to move the said piston to dispense discrete and selectable doses of insulin from the cartridge at each incremental movement of the plunger
- c. a generally cylindrical push sleeve journaled within the said body member for axial movement with respect to said body member
- d. a pair of opposed clamp members mounted for radial movement within the said body member and which can be moved radially inwardly to positively engage the said plunger in the forward direction of travel of the push sleeve whereby the plunger is driven forward by the said sleeve, but which can be moved radially outwardly to disengage from the said plunger for the rearward movement of the said sleeve to permit relative axial movement between the push sleeve and the plunger in at least the rearward direction of travel of the said push sleeve
- e. cam means operable from the exterior of the said body member and requiring positive operation for moving the said clamp members radially inward or outward
- f. an inwardly directed shoulder within the body member which acts as a stop means against which the push member or the clamp members butt at the extreme of the plunger's forward travel on each of its incremental movements
- g. an external rotatable member co-axial with the said body member for rotating the said sleeve member and causing it to move axially under the influence of a screw thread mechanism co-operating between the said body and the said sleeve whereby the sleeve can be moved rearwardly to a selected extent from the said stop shoulder when the clamp members are disengaged from the said plunger and thereby select the extent of forward travel of the plunger when the clamp members are re-engaged with the plunger for forward movement thereof.

11. A hand portable device for dispensing a fluid from a container by means of the axial movement of a piston within the container under the influence of a plunger moved by the device, which device is adapted to receive the container at its forward end and to move the plunger axially forward toward the container so as to dispense a selected amount of fluid from the container upon each actuation of the device, characterised in that the device comprises a drive mechanism adapted to be reciprocated axially of the device and to be positively engaged with the plunger for the forward stroke of the drive mechanism so as to prevent relative movement between the plunger and the drive mechanism and to move the plunger forward, which drive mechanism requires a positive action to disengage it from the plunger so as to permit relative movement between the plunger and drive mechanism for at least rearward

SAN00761634

4,865,591

17

movement of the drive mechanism; in that the forward travel of the drive mechanism is limited by a fixed stop mechanism; and in that the extent of the forward stroke of the drive mechanism is individually selectable for each actuation of the device by withdrawing the drive mechanism or a part operatively associated, therewith a selected distance from a fixed stop defined by said fixed stop mechanism.

12. A hand portable device for dispensing a fluid from a container by means of the axial movement of a piston within the container under the influence of a plunger moved by the device, which device is adapted to receive the container at its forward end and to move the plunger to dispense a selected amount of fluid from the container upon each actuation of the device, characterized in that the device by axially moving said drive mechanism a selected amount relative to said plunger while said drive mechanism is disengaged therefrom comprises:

- i. a disengageable drive mechanism adapted to be reciprocated axially of the device and adapted to positively engage the plunger whereby the plunger can be moved axially forward by the drive mechanism and to be disengaged from the plunger to permit relative axial movement between the drive mechanism and the plunger;
- ii. a disengagement means for selectively engaging or disengaging the drive means from the plunger;
- iii. an actuating means, which may be the integral with or separate from the disengagement means, for actuating the disengagement means, which actuation means requires a positive operation from a user of the device to engage and/or disengage the drive mechanism from the plunger; and
- iv. means for individually selecting the extent of travel of the drive mechanism for each actuation of the device so as to control the extent of axial movement, of the plunger upon actuation of the device.

13. A hand portable device for dispensing a fluid from a container by means of the axial movement of a piston within the container under the influence of a plunger moved by the device, which device is adapted to receive the container on its forward end and to move the plunger axially forward towards or within the container so as to dispense a selected amount of fluid from the container upon each actuation of the device, characterized in that the device comprises:

- a. an elongated generally cylindrical hollow body member, having its forward end adapted to receive and retain the fluid container;
- b. a plunger extending axially within said body member and adapted to be moved axially in a series of individually selected increments and to bear against the piston within the container when mounted on the said body member so as to move the said piston to dispense doses of fluid from the container at each incremental movement of the plunger;

18

c. a radially acting jaw member, adapted to be moved into engagement with the said plunger to provide a positive drive connection between said jaw and said plunger, and to be disengaged from said plunger so as to permit relative axial movement between said plunger and said jaw;

d. means requiring positive operation by a user of the device for engaging or disengaging said jaw from said plunger;

e. an axially acting push sleeve journaled upon said plunger for moving said jaw forward when engaged to said plunger;

f. axially acting dosage selection means comprising a screw thread moved sleeve journaled for axial movement upon said push sleeve and carrying demountable means for engaging said jaw when said latter is disengaged from said plunger and for moving it rearwardly from a datum point so as to select the possible extent of forward travel of said plunger and to release said jaw when said jaw is re-engaged with said plunger for axial movement by said push sleeve; and

g. means for rotating said screw sleeve so as to select the extent of rearward movement of said screw sleeve from said datum point.

14. A device as claimed in claim 11 wherein the plunger carries an axial series of transverse teeth and the drive mechanism carries corresponding teeth adapted to engage the teeth on the plunger when in the drive engaged position.

15. A device as claimed in claim 11 wherein the drive mechanism is actuated by a radially acting cam means which acts to move the mechanism radially inward to engage the plunger and to retain it in engagement with said plunger during forward movement of the plunger.

16. A device as claimed in claim 11 wherein the device is provided with means for positively acting on said plunger so as to prevent rearwards movement of said plunger at all times when a container is mounted on the device.

17. A device as claimed in claim 11 wherein said datum point is provided by a stop means against which a component selected from the drive mechanism and a part operatively associated therewith butts at the extreme of the forward travel of plunger on each of its incremental movements.

18. A device as claimed in claim 11 wherein there is provided a second stop means carried by said plunger which is engaged by a component selected from the drive mechanism and a part operatively associated therewith as it is retracted, whereby the second stop member prevents the drive mechanism from being withdrawn to its full extent if the residual potential travel of the plunger is less than the desired dose.

19. A device as claimed in claim 11 having a container containing a medicament is mounted at its forward end.

• • • • •

60

65



D

Q

Docket No. 5533.200-US

3763

SKADDEN, ARPS, SLATE, MEAGHER & FLOM
Four Times Square
New York, NY 10036-6522

Telephone: (212) 735-3020
Facsimile: (917) 777-3020

T-H.
6-14-01
#10/Ext
of
file
(3ms)

Date: June 6, 2001

Applicant(s) : Buch-Rasmussen et al.
Serial No. : 09/349,748 Examiner: Simons, K.
Filed : July 8, 1999 Art Unit: 3763
Title : Medical Device

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on June 6, 2001.

Robert B. Smith

Reg. No. 28,538

Robert B. Smith
Signature

June 6, 2001
Date

RECEIVED
JUN 13 2001
TECHNOLOGY CENTER 3700

Transmitted herewith is an AMENDMENT in the above-identified application.

1. () No additional fee is required.

06/11/2001 TGEDARU1 00000044 192365 09349748
FL:117 890.00 CH

(3ms)
Jail. Ash

SAN00761636

Docket No. 5533.200-US

2. () The fee has been calculated as shown below:

<u>Claims remaining</u>	<u>Prior Paid Claims</u>	<u>Extra</u>	<u>Rate</u>	<u>Fee</u>
Total:	minus (at least 20) =	@	\$18	= \$
Independent	minus (at least 3) =	@	\$80	= \$
TOTAL ADDITIONAL FEE: \$				

3. (X) An extension of time to respond to the PTO Communication dated December 7, 2000 is hereby requested. The required fee is indicated below:

Within first month:	()	\$110
Within second month	()	\$390
Within third month	(X)	\$890
Within fourth month	()	\$1,390

4. () The Amendment includes an Information Disclosure Statement. Enclosed is Form PTO-1449 and copies of ____ reference(s).
5. (X) The Commissioner is hereby authorized to charge the amount of \$ 890.00 representing (a) additional claims fee (\$); (b) the extension fee (\$ 890); and (c) the fee for filing an Information Disclosure Statement (\$) to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.
6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.
7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 19-2385. A copy of this sheet is enclosed.

Skadden, Arps, Slate, Meagher & Flom

By Robert B. Smith
 Robert B. Smith
 Registration No. 28,538
 Attorneys for Applicant(s)
 (212) 735-3020



Docket No. 5533.200-US

T.H.
6-14-01
#11/Amclt
B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Buch-Rasmussen et al.
Serial No. : 09/349,748 Examiner: Simons, K.
Filed : July 8, 1999 Art Unit: 3763
Title : Medical Device

6/14/2001 THAKIM 00000001 19238
FC:103 234.00 CH
FC:102 80.00 CH

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on June 6, 2001.

Robert B. Smith

Reg. No. 28,538

Robert B. Smith
Signature

June 6, 2001
Date

RECEIVED
JUN 13 2001
TECHNOLOGY CENTER 3709

June 6, 2001

AMENDMENT

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

In response to the Office Action dated December 7, 2000, please
amend the above-identified application as follows:

IN THE SPECIFICATION:

Replace the paragraph appearing on page 1, lines 15-23 with the
following paragraph:

B

SAN00761638

Docket No. 5533.200-US

1
B' One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly, thereby delivering the medication. When the medication in the cartridge is exhausted, the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be replaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

[
Replace the paragraph appearing on page 6, lines 8-14 with the following paragraph:

1
B2 The dosing assembly 6 is illustrated in Figs. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means and, accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment, the dosing assembly 6 includes a cylindrical housing 17 surrounding the plunger means of the dosing unit and having opposed proximal and distal ends.

Docket No. 5533.200-US

IN THE CLAIMS:

Replace claim 1 with the following claim:

1. (Amended) A medication delivery device comprising:

63 a cartridge assembly having a distal end and a proximal end, said distal end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and said cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a plunger means for acting on said stopper and a dose-setting and injection mechanism for setting a specified dose and for driving said plunger means to deliver the selected dose, and

a needle assembly including a coupling means for engaging the coupling means of said cartridge assembly to form a releasable coupling between said needle assembly and said cartridge assembly,

wherein the cartridge assembly and the dosing assembly are releasably coupled together, and wherein the combination of couplings between the dosing assembly and the cartridge assembly, and between the needle assembly and the cartridge assembly, respectively, is selected to secure that the plunger means abuts on the stopper during coupling and decoupling of the needle assembly.

Docket No. 5533.200-US

Add the Following New Claims (19-33):

19. A medication delivery device according to claim 1, wherein the plunger means comprises a rod element adapted to exert an axial movement on the stopper towards the sealed end of the cartridge.

B4
20. A medication delivery device according to claim 19, wherein the means for releasably coupling the dosing assembly and the cartridge assembly together are such that the coupling and decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

sub 2
21. A medication delivery device according to claim 20, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

22. A medication delivery device according to claim 21, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

23. A medication delivery device according to claim 1, wherein the dosing assembly comprises a scale.

24. A medication delivery device according to claim 1, wherein the dosing assembly comprises a dose setting mechanism for setting a selected dose of medication to be delivered.

Docket No. 5533.200-US

25. A medication delivery device according to claim 1, wherein the cartridge assembly comprises a housing.

26. A medication delivery device according to claim 1, wherein the cartridge assembly includes a cartridge which is unitarily molded with at least one coupling means.

27. A medication delivery device according to claim 1, further comprising a cap for protecting the needle assembly and/or cartridge assembly.

28. A medication delivery device comprising:

- a cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,
- a dosing assembly comprising a plunger means for acting on said stopper and a dose-setting and injection mechanism for setting a specified dose and for driving said plunger means to deliver the selected dose, and
- a needle assembly,
- a first releasable coupling between the needle assembly and the cartridge assembly, and
- a second releasable coupling between the cartridge assembly and the dosing assembly, wherein said first and second releasable couplings are of different types such that releasing or attaching said needle assembly onto said cartridge assembly does not urge said second releasable coupling to disengage.

Docket No. 5533.200-US

29. A medication delivery device according to claim 28, wherein said first and second couplings are each selected from the group consisting of snap locks, snap locks with guide wire, sideways snap locks, snap locks released through threads, bayonet couplings, luer locks, hinged locks and threads.

30. A medication delivery device according to claim 28, wherein said device has a longitudinal axis, wherein one of said couplings is disengaged through a relative twisting force about said axis, and wherein the other of said couplings is disengaged through a force other than twisting about said axis.

31. A medication delivery device comprising:

a cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a housing and a plunger means movable relative to said housing for acting on said stopper,

a needle assembly,

a first releasable coupling between the needle assembly and the cartridge assembly, and a second releasable coupling between the cartridge assembly and the dosing assembly housing, wherein said first and second releasable couplings are of different types such that releasing or attaching said needle assembly onto said cartridge assembly does not urge said second releasable coupling to disengage.

32. A medication delivery device according to claim 31, wherein said first and second couplings are each selected from the group consisting of snap locks,

D O
Docket No. 5533.200-US

BY
Czech

snap locks with guide wire, sideways snap locks, snap locks released through threads, bayonet couplings, luer locks, hinged locks and threads.

33. A medication delivery device according to claim 31, wherein said device has a longitudinal axis, wherein one of said couplings is disengaged through a relative twisting force about said axis, and wherein the other of said couplings is disengaged through a force other than twisting about said axis.

Docket No. 5533.200-US

REMARKS

By the foregoing amendments, two minor changes have been made to the specification. Claim 1 has been rewritten to specify that the coupling between the cartridge assembly and dosing assembly is releasable, and to specify that the dosing assembly includes a mechanism to set the dose and drive the plunger means. Also, the language concerning the means for securing that the plunger remain in contact with the stopper has been rewritten for clarity, but such limitation is believed to have the same scope as in original claim 1. The dependent claims recite various limitations of original dependent claims 2-12. Finally, new independent claims 28 and 31, and dependent claims 29-30 and 32-33 are presented. Favorable consideration of the amended claims is respectfully requested in light of the following remarks.

The present invention is directed to a specific type of medication delivery device, namely, one in which both the needle assembly and the cartridge are replaceable, but in which the needle needs to be replaced more often than the cartridge. In known devices of this type, the cartridge is sealed at its forward end by a pierceable seal, and at its other end by a slideable rubber stopper. In order to inject a dose of medicine, a double pointed needle is mounted on the forward end of the cartridge assembly such that its proximal end penetrates the seal. A plunger rod, whose forward end abuts the rubber stopper, is then advanced a specified distance to push the stopper forward and eject a corresponding dose of medicine out through the

B

Docket No. 5533-200-US

needle. In order to set the size of the dose, such devices typically include a dose-setting mechanism which will ensure that the piston rod advances a distance exactly corresponding to the size of the desired dose.

In order to deliver a precise dose, it is critical that the plunger rod, during normal use of the device (i.e., except when replacing the cartridge) remain in contact with the rubber stopper. In other words, if, between injections, a gap develops between the forward end of the piston rod and the stopper, when the next injection is made an incomplete dose will be delivered, because part of the plunger's movement will be closing such gap, rather than pressing the rubber stopper forward.

As discussed in the specification, EP 688,571 (the U.S. counterpart of which is patent No. 5,725,508) discloses a syringe having a replaceable cartridge holder, which contains a cartridge, and a replaceable needle assembly. The cartridge holder is coupled to the syringe body by threads. The needle assembly is also coupled to the syringe body by threads. Such syringe is designed to provide multiple injections from the same cartridge, and such that the needle assembly will be replaced several times before the cartridge needs to be replaced (insulin needle manufacturers in fact recommend replacing the needle after each injection).

Because the same type of coupling, i.e., a threaded coupling, is used for both connections, there is the possibility that, when the needle assembly is unscrewed from the syringe, the cartridge holder might become partially unscrewed



Docket No. 5533.200-US

from the syringe body. If that were to occur, a gap would form between the plunger rod and the rubber stopper.

Claim 1 as amended is directed to a device which includes a dose-setting and injection mechanism in which the size of the dose to be administered is set prior to the injection, and in which the mechanism advances the plunger means, e.g., plunger rod 7, to expel the set dose. In this manner, the device can be used to inject multiple injections from each cartridge, with the needle assembly being changed as often as needed. A pair of releasable couplings are provided between the needle assembly and cartridge assembly and between the cartridge assembly and dosing assembly, respectively. While either coupling can be any type of suitable coupling, Specification page 4, lines 15-16, the combination is selected to secure that the plunger means abuts on the stopper during coupling and decoupling of the needle assembly. In other words, once one coupling is chosen, the other coupling is selected so that the disengagement mechanisms of the two couplings act independent of one another, so as to ensure that coupling or decoupling of the needle assembly/cartridge assembly coupling does not cause the other coupling to disengage or partially disengage.

Original claim 1 was rejected as anticipated by Reynolds U.S. patent No. 5,364,369. Reynolds discloses a two-component syringe for mixing dry and wet components, and injecting the mixture. In particular, referring to Figures 3 and 4 of Reynolds, the Reynolds device includes a vial 6, having a seal 5 at its forward end

Docket No. 5533.200-US

and a slidable stopper 18 at its rear end. A dry medicament is held in the sealed space between the seal 5 and the stopper 18.

A capsule 14 is provided holding the liquid component to be mixed with the dry component. In order to mix the components, a cap 12, containing a double pointed needle 44, is positioned over the forward end of the capsule 14, but such that its needle 44 also does not initially penetrate the capsule 14. The cap 12 and capsule 14 are then inserted into a sleeve 10, which sleeve is screwed onto the stopper 18. Thereafter, the capsule 14 is pressed into the sleeve 10, so that the needle 44 penetrates both the capsule and a septum in the stopper 18. The liquid component can then be squeezed out of the capsule 14 and into the compartment holding the dry component, as shown in Figure 4.

Once the components have been mixed, the capsule 14 and cap 12 are withdrawn from the sleeve 10, as shown in Figure. 5, and discarded. Another cap 2, containing a backward pointing needle 22, is positioned over the forward end of the vial 6, but such that the needle 22 does not initially penetrate the seal 5. Finally, as shown in Figure 6, after mounting an optional injection needle 28 on the cap 2, the user simultaneously grabs the flanges 24 and 26 on the sleeve 10 and the cap 2, respectively, and squeezes the flanges 24, 26 towards one another. The action of pulling the cap 2 backwards causes the needle 22 to penetrate the seal 5, thereby establishing an outlet for the mixed contents in the vial 6 through the needles 22 and

B

Docket No. 5533.200-US

28. The action of pushing the sleeve 10 forward pushes the stopper 18 forward to discharge the contents of the syringe out through the needle 28.

Reynolds discloses, as an option, that the cap 2 can be mounted on the vial 6 by threads. Reynolds col. 8, lines 13-20. Thus, either there is no coupling between the cap 2 and vial 6, or both the cap 2 and the sleeve 10 are coupled to the vial 6 by the same type of coupling, i.e., threads. Moreover, Reynolds does not disclose any mechanism for setting the size of the dose or for pressing the sleeve 10 forward. For such reasons, the applicants respectfully submit that Reynolds does not disclose the apparatus recited in amended claim 1

Also, in Reynolds, the entire dose is delivered in one injection. Thus, the possibility that the coupling between a dosing assembly and a cartridge assembly might partially disengage while mounting or removing a needle assembly is not a concern. For such reasons, the applicants respectfully submit that Reynolds also does not suggest the apparatus recited in amended claim 1, and favorable consideration and allowance of claim 1 are respectfully requested.

New independent claim 28 also recites a device with a dose-setting and injection mechanism. New independent claim 31 recites that the dosing assembly includes a housing, which is coupled to the cartridge assembly, and a plunger which is movable relative to the housing. In addition, such claims recite that the first and second couplings, between the needle assembly/cartridge assembly and cartridge assembly/dosing assembly, respectively, are of different types so as not to interact

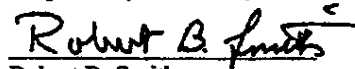
Docket No. 5533.200-US

with one another. Such features are not disclosed or suggested in Reynolds, and favorable consideration of such claims are respectfully requested.

Favorable consideration and allowance of the dependent claims are respectfully requested for the reasons set forth in the parent claims, as well as the additional novel features recited therein.

For the reasons discussed above, entry of the proposed amendments, and favorable reconsideration and allowance of the application, are respectfully requested.

Respectfully submitted,



Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)

Skadden, Arps, Slate, Meagher, & Flom
Four Times Square
New York, NY 10036-6522
(212) 735-3020



Docket No. 5533.200-US

VERSION WITH MARKINGS TO SHOW CHANGES MADE
CHANGES IN THE SPECIFICATION:

Paragraph appearing on page 1, lines 15-23:

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly, thereby delivering the medication. When the medication in the cartridge is exhausted, the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be replaced [displaced] by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

Paragraph at page 6, lines 8-14:

The dosing assembly 6 is illustrated in Figs. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means[,] and, accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment, the dosing assembly 6 includes a cylindrical housing 17 surrounding the plunger means [17] of the dosing unit and having opposed proximal and distal ends.

B

Docket No. 5533.200-US

CHANGES IN THE AMENDED CLAIMS

1. (Amended) A medication delivery device comprising:

a cartridge assembly[,] having a distal end and a proximal end [one end sealed with a pierceable sealing], said distal end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and said cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a plunger means for acting on said stopper and a dose-setting and injection mechanism for setting a specified dose and for driving said plunger means to deliver the selected dose, and

[and optionally] a needle assembly including a coupling means for engaging the coupling means of said cartridge assembly to form a releasable coupling between said needle assembly and said cartridge assembly.

wherein the cartridge assembly and the dosing assembly are releasably coupled together, and [the device further comprises means for securing] wherein the combination of couplings between the dosing assembly and the cartridge assembly, and between the needle assembly and the cartridge assembly, respectively, is selected to secure that the plunger means abuts on the stopper during [use of the device] coupling and decoupling of the needle assembly.

B



UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER OF PATENTS AND TRADEMARKS
 Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/349,748 07/08/99 BUCH-RASMUSSEN T 5533.200-US

STEVE T ZELSON ESQ
 NOVO NORDISK OF NORTH AMERICA INC
 SUITE 6400
 405 LEXINGTON AVENUE
 NEW YORK NY 10174-6400

QM32/0824

EXAMINER

SIRMONS, K

ART UNIT	PAPER NUMBER
----------	--------------

3763

DATE MAILED: 08/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)	
09/349,748	BUCH-RASMUSSEN ET AL	
Examiner	Art Unit	
Kevin C. Simons	3763	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 19-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 19-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

U.S. Patent and Trademark Office
 Office of Primary Examiner

SAN00761654

Application/Control Number: 09/349,748
Art Unit: 3763

Page 2

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "injection mechanism" must be clearly shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 1 and 28, it is unclear what applicant regards as the injection mechanism.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 and 19-27 are rejected under 35 U.S.C. 102(b) as being anticipated by

Chanoch U.S. Pat. No. 5,688,251.

Application/Control Number: 09/349,748
Art Unit: 3763

Page 3

Chanoch discloses a medication delivery device comprising: a cartridge assembly having a distal end and a proximal end (300), said distal end of the cartridge assembly comprising coupling means (303) for releasably mounting a needle assembly, and said cartridge assembly comprising a cartridge having one end with a pierceable seal (fig. 2 and 3) and having a stopper (125 or 355) adapted to receive a plunger means (figs. 1-4), a dosing assembly (figs. 1-4) comprising a plunger means for acting on said stopper and a dose-setting and injection mechanism for setting a specified dose and for driving said plunger means to deliver the selected dose (figs. 1-4), and a needle assembly including a coupling means for engaging the coupling means of said cartridge assembly to form a releasable coupling between said needle assembly and said cartridge assembly (figs. 1-4), wherein the cartridge assembly and the dosing assembly are reliably coupled together, and wherein the combination of couplings between the dosing assembly and the cartridge assembly, and between the needle assembly and the cartridge assembly, respectively, is selected to secure that the plunger means abuts on the stopper during coupling and decoupling of the needle assembly (figs. 1-4); as to claims 2-12 and 19-27, (figs. 1-4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

SAN00761656

Application/Control Number: 09/349,748
Art Unit: 3763

Page 4

Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery device substantially as claimed, however, it is not clear if Chanoch discloses a first and second releasable couplings that are of different types. Nevertheless, Chanoch clearly discloses other means for mounting the needle assembly to the cartridge assembly may be used (col. 8, lines 15-20). Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to modify the releasable couplings of Chanoch to have various and different types of connections for quicker disconnection.

Response to Arguments

Applicant's arguments with respect to claim 1-13 and 19-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed.

Application/Control Number: 09/349,748

Page 5

Art Unit: 3763

and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703)306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS
Kevin C. Sirmons
Patent Examiner
8/22/01


RICHARD K. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

SAN00761658

Form PTO 948 (Rev. 8-98)

U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office

Application No. 349,748NOTICE OF DRAFTSPERSON'S
PATENT DRAWING REVIEWThe drawing(s) filed (insert date) 7/8/99 are:A. ☐ approved by the Draftsperson under 37 CFR 1.84 or 1.152.B. ☒ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be submitted according to the instructions on the back of this notice.

<p>1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color. Color drawings are not acceptable until position is granted. Fig(s) _____ Pencil and non black ink not permitted. Fig(s) _____ 2. PHOTOGRAPHS. 37 CFR 1.84(b) 1 full-tone set is required. Fig(s) _____ Photographs not properly mounted (must use bristol board or photographic double-weight paper). Fig(s) _____ Poor quality (half-tone). Fig(s) _____ 3. TYPE OF PAPER. 37 CFR 1.84(c) Paper not flexible, strong, white, and durable. Fig(s) _____ Erasures, alterations, overwriting, interlineations, folds, copy machine marks not accepted. Fig(s) _____ Mylar, vellum paper is not acceptable (too thin). Fig(s) _____ 4. SIZE OF PAPER. 37 CFR 1.84(d): Acceptable sizes: 21.0 cm by 29.7 cm (DIN size A4) 21.6 cm by 27.9 cm (8 1/2 x 11 inches) All drawing sheets not the same size. Sheet(s) _____ Drawings sheets not on acceptable size. Fig(s) _____ 5. MARGINS. 37 CFR 1.84(e): Acceptable margins: Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm SIZE: A4 Size Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm SIZE: 8 1/2 x 11 Margins not acceptable. Fig(s) _____ Top (T) _____ Left (L) _____ Right (R) _____ Bottom (B) _____ 6. VIEWS. 37 CFR 1.84(h) REMINDER: Specification may require revision to correspond to drawing changes. Partial views. 37 CFR 1.84(h)(2) Brackets needed to show figure as one entity. Fig(s) _____ Views not labeled separately or properly. Fig(s) _____ Enlarged view not labeled separately or properly. Fig(s) _____ 7. SECTIONAL VIEWS. 37 CFR 1.84(h)(3) Hatching not indicated for sectional portions of an object. Fig(s) _____ Sectional designation should be noted with Arabic or Roman numerals. Fig(s) _____</p>	<p>8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i) Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) _____ 9. SCALE. 37 CFR 1.84(j) Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s) _____ 10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(k) Lines, numbers & letters not uniformly thick and well defined, clean, durable and black (poor line quality). Fig(s) <u>2, 4, 10, 11</u> 11. SHADING. 37 CFR 1.84(m) Solid black areas pale. Fig(s) _____ Solid black shading not permitted. Fig(s) _____ Shade lines, pale, rough and blurred. Fig(s) _____ 12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p) Numbers and reference characters not plain and legible. Fig(s) _____ Figure legends are poor. Fig(s) _____ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(1) - 1 Fig(s) _____ English alphabet not used. 37 CFR 1.84(p)(2) Fig(s) _____ Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig(s) _____ 13. LEAD LINES. 37 CFR 1.84(q) Lead lines cross each other. Fig(s) _____ Lead lines missing. Fig(s) _____ 14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(r) Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Sheet(s) _____ 15. NUMBERING OF VIEWS. 37 CFR 1.84(s) Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) _____ 16. CORRECTIONS. 37 CFR 1.84(w) Corrections not made from prior PTO-948 dated _____ 17. DESIGN DRAWINGS. 37 CFR 1.152 Surface shading shown not appropriate. Fig(s) _____ Solid black shading not used for color contrast. Fig(s) _____</p>
--	---

COMMENTS

REVIEWER S. F. Zild DATE 12/23/99 TELEPHONE NO. 703 305-8335

ATTACHMENT TO PAPER NO. _____

SAN00761659

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities--37 CFR 1.85

File new drawings with the changes incorporated therein. The application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application, should be placed on the back of each sheet of drawings in accordance with 37 CFR 1.84(c). Applicant may delay filing of the new drawings until receipt of the Notice of Allowability (PTOL-37). Extensions of time may be obtained under the provisions of 37 CFR 1.136. The drawing should be filed as a separate paper with a transmittal letter addressed to the Drawing Processing Branch.

2. Timing for Corrections

Applicant is required to submit acceptable corrected drawings within the three-month shortened statutory period set in the Notice of Allowability (PTOL-37). If a correction is determined to be unacceptable by the Office, applicant must arrange to have acceptable corrections resubmitted within the original three-month period to avoid the necessity of obtaining an extension of time and paying the extension fee. Therefore, applicant should file corrected drawings as soon as possible.

Failure to take corrective action within set (or extended) period will result in ABANDONMENT of the Application.

3. Corrections other than Informalities Noted by the Drawing Review Branch on the Form PTO-948

All changes to the drawings, other than informalities noted by the Drawing Review Branch, MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

APPROVED	C.B.T.
BY	CLASS.
DRAFTSMAN	

2/2

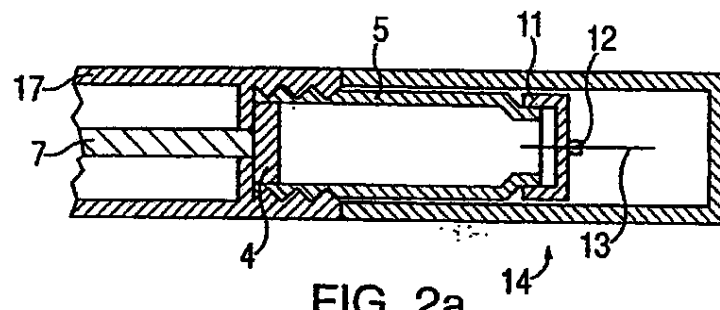


FIG. 2a

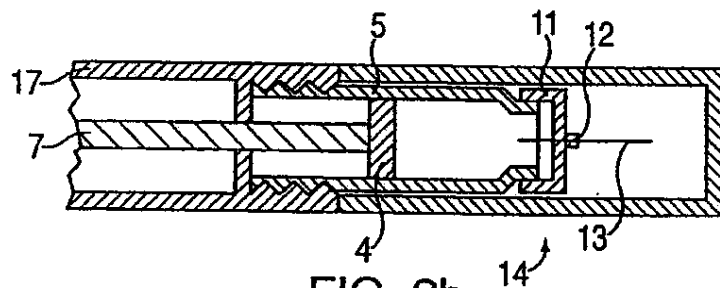


FIG. 2b

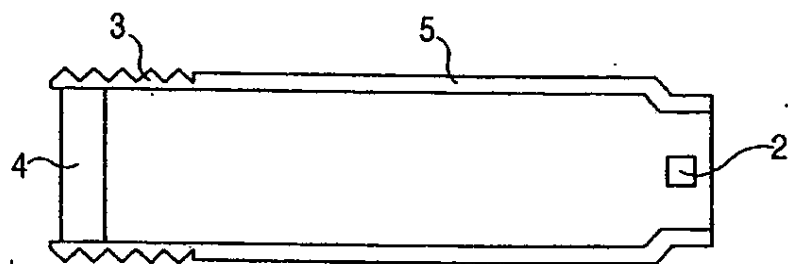


FIG. 3

09/349 748
Buch-Rasmussen et



RECEIVED

JAN 9 6 2002
TECHNOLOGY CENTER RPTC

RECEIVED

JAN 16 2002
TECHNOLOGY CENTER R3700

Docket No. 5533.200-US

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

FOUR TIMES SQUARE
NEW YORK 10036-6522

(212) 735-3000
FAX: (212) 735-2000



RECEIVED

JAN 16 2002
TECHNOLOGY CENTER
#13
Ex. of Time (1)
D. Byrce
1/17/02

Applicant(s) : Buch-Rasmussen et al.

Serial No. : 09/349,748

Examiner: Sirmons, K.

Filed : July 8, 1999

Art Unit: 3763

Title : Medical Device

**AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME**

Date: December 10, 2001

Box AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on December 10, 2001.

Robert B. Smith

Reg. No. 28,538

Robert B. Smith
Signature

December 10, 2001
Date

Transmitted herewith is an Amendment in the above-identified application.

1. () No additional fee is required.

1/14/2002 CC:HRU1 00000032 192385 09349748
17C:115 110.00 CH

SAN00761663

Docket No. 5533.200-US

2. ☐ The fee has been calculated as shown below:

<u>Claims remaining</u>	<u>Prior Paid Claims</u>	<u>Extra</u>	<u>Rate</u>	<u>Fee</u>
Total:	minus (at least 20) =	@	\$18	= \$
Independent	minus (at least 3) =	@	\$80	= \$
TOTAL ADDITIONAL FEE: \$				

3. ☒ An extension of time to respond to the PTO Communication dated August 24, 2001 is hereby requested. The required fee is indicated below:

Within first month:	<input checked="" type="checkbox"/>	\$ 110
Within second month	<input type="checkbox"/>	\$ 400
Within third month	<input type="checkbox"/>	\$ 920
Within fourth month	<input type="checkbox"/>	\$1,440
Within the fifth month	<input type="checkbox"/>	\$1,960

4. ☐ Enclosed please find a check in the amount of \$ 0.00 representing (a) additional claims fee (\$ 0) and (b) the extension fee (\$ 0).
5. ☒ The Commissioner is hereby authorized to charge the amount of \$ 110.00 representing (a) additional claims fee (\$); and (b) the extension fee (\$ 110) to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.
6. ☒ In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.
7. ☒ The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 19-2385. A copy of this sheet is enclosed.

Skadden, Arps, Slate, Meagher & Flom

By Robert B. Smith
 Robert B. Smith
 Registration No. 28,538
 Attorneys for Applicant(s)
 (212) 735-3020



Docket No. 5533.200-US #14

Amold H C
J. Byrce
1/17/02

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Buch-Rasmussen et al.

Serial No. : 09/349,748

Examiner: Simons, K.

Filed : July 8, 1999

Art Unit: 3763

Title : Medical Device

RECEIVED
JAN 16 2002
TECHNOLOGY CENTER R3700

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on December 10, 2001.

Robert B. Smith

Reg. No. 28,538

Robert B. Smith
Signature

December 10, 2001
Date

December 10, 2001

AMENDMENT AFTER FINAL REJECTION

Box AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

In response to the Office Action dated August 24, 2000, the applicants respectfully request entry of the following amendments, to render the claims allowable or at least in better form for appeal:

IN THE CLAIMS:

Cancel claims 2-18, 20, and 24.

1

SAN00761665

Docket No. 5533.200-US

Replace claims 1, 21, 25, 28, and 31 with the following claims:

1. (Twice Amended) A medication delivery device comprising:

a cartridge assembly having a distal end and a proximal end, said distal end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and said cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a plunger means for acting on said stopper, a mechanism for setting a specified dose, and a driving means for advancing said plunger means to deliver the set dose, and

a needle assembly including a coupling means for engaging the coupling means of said cartridge assembly to form a releasable coupling between said needle assembly and said cartridge assembly,

wherein the cartridge assembly and the dosing assembly are releasably coupled together, and wherein the combination of couplings between the dosing assembly and the cartridge assembly, and between the needle assembly and the cartridge assembly, respectively, is selected to ensure that the force applied to couple and decouple said needle assembly to and from said cartridge assembly does not cause said dosing assembly to move away from said cartridge assembly during coupling and decoupling of said needle assembly, such that said plunger means remains in abutment with said stopper during such coupling and decoupling.

Docket No. 5533.200-US

C₂
21. (Amended) A medication delivery device according to claim 1,
wherein the dosing assembly is released from the cartridge assembly through a
movement including an axial movement.

C₃
25. (Amended) A medication delivery device according to claim 1,
wherein the cartridge assembly comprises a housing for receiving a cartridge.

C₄
28. (Amended) A medication delivery device comprising:
a cartridge assembly comprising a cartridge having one end sealed
with a pierceable seal and having a stopper adapted to receive a plunger means,
a dosing assembly comprising a plunger means for acting on said
stopper, a mechanism for setting a specified dose, and a drive means for advancing
said plunger means to deliver the set dose, and
a needle assembly,
a first releasable coupling between the needle assembly and the
cartridge assembly, and
a second releasable coupling between the cartridge assembly and the
dosing assembly, wherein said first and second releasable couplings are of different
types and are selected such that the force applied to couple and decouple said needle
assembly to and from said cartridge assembly does not urge said second releasable
coupling to disengage, thereby ensuring that said dosing assembly does not move
away from said cartridge assembly during coupling and decoupling of said needle
assembly, such that said plunger means remains in abutment with said stopper.

Docket No. 5533.200-US

31. (Amended) A medication delivery device comprising:

a cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a housing and a plunger means movable relative to said housing for acting on said stopper,

a needle assembly,

a first releasable coupling between the needle assembly and the cartridge assembly, and a second releasable coupling between the cartridge assembly and the dosing assembly housing, wherein said first and second releasable couplings are of different types and are selected such that the force applied to couple and decouple said needle assembly to and from said cartridge assembly does not urge said second releasable coupling to disengage, thereby ensuring that the dosing assembly does not move away from the cartridge assembly during coupling and decoupling of said needle assembly, such that said plunger means remains in abutment with said stopper.

Docket No. 5533.200-US

REMARKS

Enclosed herewith is a new sheet of formal drawings containing Figs. 2a, 2b, and 3, which is submitted to overcome the objection raised in the Notice of Draftsperson's Patent Drawing Review.

The applicants respectfully request entry of the foregoing amendments to the claims. By the foregoing amendments, the non-elected claims (13-18) would be canceled, along with dependent claims 2-12, 20, and 24. In addition, independent claims 1 and 28 would be amended to overcome the rejection under 35 U.S.C. § 112 (i.e., that it is unclear what the applicant regards as the injection mechanism). As amended, such claims would recite a mechanism for setting a specified dose, e.g., dose setting wheel 9, and a "driving means" for advancing the plunger means (e.g., plunger rod 7). As disclosed in the specification on page 6, the "driving means" includes the actuator button 18 together with any suitable mechanism for advancing the plunger rod element 7 in response to actuating the actuator button 18. Page 6, lines 18-25.

The Examiner objected to the drawings as not showing an "injection mechanism." As noted above, the term "injection mechanism" has been replaced by the term "driving means" for clarity. The drawings expressly show part of a suitable "driving means," in the form of the actuator button 18. Page 6, lines 24-25. Moreover, the specification discloses that the remaining part of the driving mechanism is contained in the dosing assembly housing 17. Page 6, lines 12-25. Thus, element 17

C

Docket No. 5533.200-US

schematically depicts the remaining parts of the "driving means." Because driving mechanisms which advance the plunger rod in response to depressing an actuator button are well known, and because the specification discloses that any suitable driving mechanism may be employed, Page 6, lines 12-25, the applicants respectfully submit that the drawings need only show such mechanism schematically, as the current drawings do. Thus, the applicants respectfully request reconsideration of the objection to the drawings in light of the change in terminology in claims 1 and 28.

By the foregoing amendments, independent claims 1, 28, and 31 would be amended to clarify the function of selecting the first and second couplings in the manner already specified in those claims, in order to point out more clearly the novel features of the claimed invention.

In the device according to claims 1, 28, and 31, a plunger means, such as a rigid or flexible piston rod, pushes a movable stopper in the cartridge barrel in a forward direction in order to administer set doses of medicine. A dose setting mechanism is used to set the size of the dose. When the dose is administered, the piston rod is pushed forward a distance proportional to the set dose, pushing the stopper forward by exactly the same distance. In order to administer accurate doses, it is essential that, between doses, the forward end of the piston rod is not allowed to retract from the stopper. If that were to occur, the initial portion of the piston rod movement, when administering the next dose, would merely close the gap between

C

Docket No. 5533.200-US

the piston rod and the stopper. Because less than the entire movement of the piston rod would push the stopper, a dose smaller than the set dose would be administered.

In conventional durable insulin syringes ("durable" meaning that the cartridge can be replaced), the cartridge assembly is coupled to the dosing assembly by threads. A needle assembly is also removably mounted on the cartridge assembly by threads. The former coupling allows the cartridge (or the entire cartridge assembly, if the cartridge assembly does not contain a separate cartridge holder, such as is shown in Figs. 1-3 of the present application) to be changed when empty. The latter coupling permits the needle to be removed from the device after a dose has been administered, and replaced when a new dose is to be administered.

Because the two threaded couplings are coaxial with one another, if the user grasps the dosing assembly housing when screwing or unscrewing the needle assembly, the cartridge assembly may rotate relative to the dosing assembly housing. If this occurs, the dosing assembly will move, at least by a small distance, in a direction away from the cartridge assembly, causing the piston rod to move axially away from the stopper. And, if the user does not notice such separation, and does not screw the cartridge assembly back into its original, seated position in the dosing assembly, as noted above the next dose administered will be less than the set dose, because the initial segment of the forward movement of the plunger rod will merely close the gap between the plunger rod and the cartridge stopper, rather than push the stopper forward to expel medicine.

Docket No. 5533.200-US

The possibility that mounting or removing the needle assembly will cause the plunger to retract from the stopper is eliminated in the device claimed in claims 1, 28, and 31.

As recited in claim 1, the couplings between the needle assembly and cartridge assembly, on the one hand, and between the cartridge assembly and the dosing assembly, on the other hand, are chosen so as to ensure that the cartridge assembly does not move away from the dosing assembly during coupling and decoupling of the needle assembly. In other words, such couplings are chosen to ensure that the act of mounting or removing the needle assembly does not cause the dosing assembly to move in a direction away from the stopper. The limitation in claim 1, that the two couplings must be chosen so that they will inherently ensure that such movement between the cartridge assembly and dosing assembly does not occur during needle mounting or removal, ensures that the plunger means will not retract from the stopper during needle mounting and removal.

Claims 28 and 31 recite a preferred structure for ensuring that the plunger will not be retracted from the stopper when changing needles. More particularly, claims 28 and 31 recite that the first and second couplings are different from one another, and further recite that the force applied to couple and decouple the needle assembly will not urge the dosing assembly/cartridge assembly coupling to disengage. In other words, the first and second couplings are chosen such that the force required to disengage the first releasable coupling is in a direction which is

Docket No. 5533.200-US

different from the force required to mount or remove the needle assembly. For example, if the first releasable coupling (between the dosing assembly and cartridge assembly) comprises threads, thus requiring a torque about the longitudinal axis to disengage such coupling, the second releasable coupling (for mounting the needle on the cartridge assembly) would not be one which uses a torque about the longitudinal axis to mount and remove the needle.

In the last Office Action, claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Chanoch U.S. patent No. 5,688,251. Claims 28 and 31 were rejected under 35 U.S.C. § 103(a) as being obvious over Chanoch. The Examiner conceded that Chanoch does not disclose the concept of using two different couplings in the same device. However, the Examiner noted that Chanoch discloses that other means for mounting the needle assembly may be used (Col. 8, lines 15-20), and concluded that it would be obvious to modify the releasable couplings of Chanoch to have two different couplings for quicker disconnection. August 24, 2001, Office Action, page 4.

With respect to the anticipation rejection of claim 1, in Chanoch, both couplings are shown as concentric threaded couplings. Therefore, a risk exists that the dosing assembly can be partly unscrewed from the cartridge assembly if the user grasps the dosing assembly housing instead of the cartridge assembly when screwing or unscrewing the needle. Thus, the example disclosed in Chanoch does not have a pair of couplings that will ensure that the dosing assembly will not move away

C

Docket No. 5533.200-US

slightly, i.e., partially separate, from cartridge assembly when the needle is screwed onto or off of the cartridge assembly, as recited in claim 1.

Although Chanoch discloses that alternate couplings can be used to mount the needle assembly on the cartridge assembly, there is no suggestion that, if a different type of coupling type is to be employed to mount the needle, it should be selected to ensure that the force applied in mounting or removing the needle cannot cause the dosing assembly to move away from the cartridge assembly, as recited in claim 1. In other words, Chanoch fails to disclose that the alternative coupling for the needle assembly should be chosen to prevent any possibility that the dosing assembly could rotate relative to the cartridge assembly, and thereby partially unscrew from the cartridge assembly, during needle mounting/removal.

To support a finding of anticipation, a reference must expressly or at least inherently disclose every element of the claim. Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). Moreover, in order for a disclosure to be "inherent," the missing descriptive matter must necessarily be present in the prior art reference such that one skilled in the art would recognize such a disclosure. *Id.* In the case of Chanoch, if a different type of coupling were to be chosen for the needle assembly, it would not necessarily ensure that movement between the doser assembly and cartridge assembly, and consequently between the plunger and stopper, is prevented. Because the features recited in claim 1 would necessarily be present if an alternative coupling were to be used for the needle

C

Docket No. 5533.200-US

assembly, the applicants respectfully submit that Chanoch does not anticipate claim

1.

Because amended claim 1 is not anticipated by Chanoch (and, for reasons discussed below in connection with claims 28 and 31, the features recited in claim 1 are not obvious), the applicants respectfully request allowance of such claim.

With respect to the obviousness rejection of claims 28 and 31, which recite specifically that the coupling pair must be chosen such that the force of mounting or removing the needle will not urge the cartridge assembly/dosing assembly coupling to disengage, the exemplary embodiment in Chanoch does not provide a combination of couplings wherein screwing the needle onto or off of the cartridge assembly will not urge the other coupling to disengage, as recited in claims 28 and 31. In Chanoch, if the user grasps the dosing housing while screwing the needle onto the cartridge assembly housing or unscrewing the needle from such housing, such twisting force will be transmitted across the cartridge assembly/dosing assembly threaded coupling. In one of the two rotational directions, i.e., either screwing the needle on or unscrewing the needle, such twisting force will urge the cartridge assembly to unscrew from the dosing assembly (even if no separation of the two syringe parts actually results).

Although, as the Examiner notes, Chanoch discloses that other couplings can be used for the needle assembly, Chanoch contains no suggestion to select an alternative coupling for the needle assembly such that the force applied in

Docket No. 5533.200-US

mounting or removing the needle will be in a direction that will not urge the coupling between the dosing assembly and cartridge assembly to disengage, as recited in claims 28 and 31.

Applicant's disclosure of selecting two couplings that do not interact with one another, i.e., where the actuation of one will never cause actuation of the other, is obvious only in hindsight. While it is true that, if a person skilled in the art were to try different couplings for the needle assembly as suggested in Chanoch, such person might discover that pairing certain couplings produces the benefits of the invention recited in claims 1, 28, and 31, it is well settled that "obvious to try" is an improper standard for determining obviousness. In re Deuel, 51 F.3d 1552, 1559, 34 U.S.P.Q.2d 1210, 1216 (Fed. Cir. 1995).

The conclusion that the invention claimed in claims 1, 28, and 31 is not obvious, except in hindsight, can no better be illustrated than by the fact that, while Chanoch discloses that other needle couplings can be employed, the only embodiment disclosed in Chanoch (i.e., the most preferable embodiment known to Chanoch) utilizes couplings where screwing and unscrewing the needle can cause the dosing assembly/cartridge assembly coupling to partly disengage. Thus, the invention claimed in claims 1, 28, and 31 was not obvious to Chanoch.

The applicants urge the entry of such language changes in claims 28, and 31, insofar as the Examiner already appears to interpret claims 28 and 31 in such a manner. With respect to claim 1, prior to amendment, such claim recited that the

1

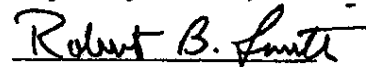
Docket No. 5533.200-US

choice of couplings "secure" that the plunger abuts the stopper when the needle is mounted or removed. The term "secure" has been changed to "ensure" for idiomatic reasons, and insofar as the Examiner, in rejecting claim 1 based on anticipation, appears to have given the phrase "secure . . ." no weight. The language revisions thus do not change the scope of the existing claims, and for such reasons entry is respectfully requested.

Finally, the applicants note that claims 1 and 28 would be amended to change the term "selected dose" to "set dose" for clarity, insofar as those claims refer previously to "setting" a dose rather than "selecting" a dose. Such amendment is thus merely of form, to conform the language used in the claim, and does not affect the scope of the claim.

For the reasons discussed above, entry of the proposed amendments, and favorable reconsideration and allowance of the application, are respectfully requested.

Respectfully submitted,



Robert B. Smith

PTO Registration No. 28,538

Attorney for applicant(s)

Skadden, Arps, Slate, Meagher, & Flom
Four Times Square
New York, NY 10036-6522
(212) 735-3020

Docket No. 5533.200-US

VERSION WITH MARKINGS TO SHOW CHANGES MADE**CHANGES IN THE AMENDED CLAIMS**

1. (Twice Amended) A medication delivery device comprising:

a cartridge assembly having a distal end and a proximal end, said distal end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and said cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a plunger means for acting on said stopper, a [and a dose-setting and injection] mechanism for setting a specified dose, and [for driving] a driving means for advancing said plunger means to deliver the [selected] set dose, and

a needle assembly including a coupling means for engaging the coupling means of said cartridge assembly to form a releasable coupling between said needle assembly and said cartridge assembly,

wherein the cartridge assembly and the dosing assembly are releasably coupled together, and wherein the combination of couplings between the dosing assembly and the cartridge assembly, and between the needle assembly and the cartridge assembly, respectively, is selected to [secure] ensure that the force applied to couple and decouple said needle assembly to and from said cartridge assembly

C

Docket No. 5533.200-US

does not cause said dosing assembly to move away from said cartridge assembly during coupling and decoupling of said needle assembly, such that said [the] plunger means [abuts on] remains in abutment with said [the] stopper during such coupling and decoupling [of the needle assembly].

21. (Amended) A medication delivery device according to claim [20] 1, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

25. (Amended) A medication delivery device according to claim 1, wherein the cartridge assembly comprises a housing for receiving a cartridge.

28. (Amended) A medication delivery device comprising:
a cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,
a dosing assembly comprising a plunger means for acting on said stopper, a [and a dose-setting and injection] mechanism for setting a specified dose, and [for driving] a drive means for advancing said plunger means to deliver the [selected] set dose, and

a needle assembly,

a first releasable coupling between the needle assembly and the cartridge assembly, and

a second releasable coupling between the cartridge assembly and the dosing assembly, wherein said first and second releasable couplings are of different

Docket No. 5533.200-US

types and are selected such that the force applied to couple and decouple [releasing or attaching] said needle assembly [onto] to and from said cartridge assembly does not urge said second releasable coupling to disengage, thereby ensuring that said dosing assembly does not move away from said cartridge assembly during coupling and decoupling of said needle assembly, such that said plunger means remains in abutment with said stopper.

31. (Amended) A medication delivery device comprising:

a cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a housing and a plunger means movable relative to said housing for acting on said stopper,

a needle assembly,

a first releasable coupling between the needle assembly and the cartridge assembly, and a second releasable coupling between the cartridge assembly and the dosing assembly housing, wherein said first and second releasable couplings are of different types and are selected such that the force applied to couple and decouple [releasing or attaching] said needle assembly [onto] to and from said cartridge assembly does not urge said second releasable coupling to disengage, thereby ensuring that the dosing assembly does not move away from the cartridge assembly during coupling and decoupling of said needle assembly, such that said plunger means remains in abutment with said stopper.